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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/773,861 | 02/01/2001 | Gregory M. Landes | GA0182US | 5135 |

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| EXAMINER | |
|---|---|
| GUNTER, DAVID R | |
| ART UNIT | PAPER NUMBER |
| 1634 | |

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/773,861 | Applicant(s) LANDES, GREGORY M. | |
|---|---|---|---|
| | Examiner David R. Gunter | Art Unit 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, drawn to a method of identifying a polynucleotide, classified in class 435, subclass 6.

II. Claims 4-18, drawn to a polynucleotide, probe, gene, gene delivery vehicle, and host cell, classified in class 536, subclass 22.1.

III. Claims 19-20, drawn to an isolated polypeptide, classified in class 530, subclass 350.

IV. Claims 21-22, drawn to an antibody, classified in class 530, subclass 387.9.

V. Claim 23, drawn to a polynucleotide of Claim 4 attached to a chip array, classified in class 435, subclass 288.3

VI. Claims 24-26, drawn to a computer readable medium, classified in class 360, subclass 135.

VII. Claims 27-28, drawn to a method of identifying a polynucleotide, classified in class 435, subclass 91.2.

VIII. Claim 29, drawn to a method of identifying a polypeptide, classified in class 436, subclass 501.

IX. Claim 30, drawn to a method of analyzing gene expression, classified in class 435, subclass 29.

X. Claim 31 and 32, drawn to a method of identifying a polynucleotide, classified in class 707, subclass 6.

1. Groups I, VII, and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Group I (Claims 1-3) recites isolation of a polynucleotide from a cell homogenate, sequencing the polynucleotide, and determining the expression level of the polynucleotide. Group VII (Claims 27-28) recites the use of a polynucleotide identified by the method of Group I as a probe for sequences complimentary to the polynucleotide. The claims recite Group I and Group VII as two distinct methods which may be used sequentially to accomplish substantially different effects (identification of a polynucleotide vs. identification of molecules which will hybridize to the previously identified polynucleotide) through substantially different modes of operation (direct sequencing and quantification vs. hybridization and amplification). For these reasons Groups I and VII are considered to be unrelated and restriction is deemed proper.

Group X (Claims 31-32) recites a method comprising searching a database for the polynucleotide identified in Group I. Unlike either Group I or Group VII, Group X comprises the steps of an electronic search of a sequence database. Because of this substantial difference in the mode of operation, Group X is considered to be unrelated to Groups I and VII. Therefore, Groups I, VII and X are unrelated to one another and restriction is deemed proper.

2. Group II is related to Groups I, VII, and X as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the methods of Groups I, VII, and X are unrelated as described above. The product (the polynucleotide of Group II) can be identified using any of these materially different processes, therefore restriction is deemed proper.

3. Groups I and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Claims 1-3 (Group I) recite a method of identifying a polynucleotide from a cell. Claim 30 (Group IX) recites the additional method steps of contacting the cell with an agent which is a putative regulator of gene expression and comparing the expression of gene in the treated cells to expression in control cells. Groups I and IX differ in their mode of operation, function, and effects, and are therefore considered to be unrelated. For this reason, restriction is deemed proper.

4. Groups II – IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Nucleotide sequences (Group II) encoding proteins (Group III) are structurally and functionally distinct chemical compounds

from the amino acid sequences they encode and so are unrelated to the protein. The nucleotide and the protein encoded are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Furthermore, antibodies are structurally and functionally distinct chemical compounds from the proteins to which they bind and so are unrelated to the protein. The antibody and the protein encoded are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Therefore Groups II – IV are unrelated due to differences in their chemical structure, properties, and potential applications, and restriction is deemed proper.

5. Groups II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Group II can be used for a plurality of materially different processes other than serving as a source of sequence information to be stored on the computer readable medium of Group VI. Other potential uses for the polynucleotide of Group II include serving as a template for PCR, identifying DNA binding proteins, or acting as a probe for Southern blots.

6. Groups III and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be

made by another and materially different process (MPEP § 806.05(f)). In the instant case the product (the polypeptide of Group III) can be identified ("made") by a number of materially different processes than the method of Group VIII including purification and sequencing of the protein.

7. Groups IV and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (the antibody of Group IV) can be used in a number of materially different processes than identification of polypeptides (Group VIII) including affinity purification of proteins.

8. Inventions VI and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (the sequence data stored in a computer readable format of Group VI) can be used in a number of materially different processes than the database search of Group X including printing the sequences for publication or submission of the sequences to GenBank or other locations.

9. Inventions IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have substantially different modes of operation. The search of a computer database (Group X) requires substantially different method steps than the treatment of cells with a putative regulator of gene expression, determining the level of gene expression, and comparing that level to the level found in untreated cells (Group IX). For this reason the methods are considered unrelated and restriction is deemed proper.

10. Groups II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (the polynucleotide of Group II) can be used in a number of materially different processes than being incorporated into the chip of Group V including acting as a template for PCR amplification, identifying DNA binding proteins, or serving as a probe in Southern or northern blots.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David R. Gunter whose telephone number is (703) 308-1701. The examiner can normally be reached on 9:00 - 5:00 M - F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-9212 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

David R. Gunter, DVM, PhD
August 14, 2002

STEPHANIE W. ZITOMER
PRIMARY EXAMINER